

Laporan praktik kerja apoteker di Kementerian Kesehatan RI di PT Combiphar di Unit Riset dan Pengembangan PT Kimia Farma Tbk di Apotek Kimia Farma = Apothecary internship report at Kementerian Kesehatan RI at PT Combiphar at Unit Riset dan Pengembangan PT Kimia Farma Tbk at Apotek Kimia Farma

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Abstrak

Praktek Kerja Profesi Apoteker di Direktorat Bina Produksi Dan Distribusi Alat Kesehatan Direktorat Jenderal Bina Kefarmasian Dan Alat Kesehatan Kementerian Kesehatan Republik Indonesia bertujuan mengetahui struktur organisasi tugas dan fungsi Direktorat Bina Produksi dan Distribusi Alat Kesehatan serta memperoleh pengetahuan mengenai peranan apoteker dalam bidang pelayanan kefarmasian khususnya dalam bidang produksi dan distribusi alat kesehatan alkes serta perbekalan kesehatan rumah tangga PKRT Direktorat Bina Produksi dan Distribusi Alat Kesehatan mempunyai tugas melaksanakan penyiapan perumusan dan pelaksanaan kebijakan dan penyusunan Norma Standar Prosedur dan Kriteria serta pemberian bimbingan teknis dan evaluasi di bidang produksi dan distribusi alkes serta PKRT Apoteker berperan sebagai tim penilai yang mengevaluasi berkas permohonan sertifikat produksi izin penyalur alkes dan izin edar alkes dan PKRT Dalam tugas khusus dijelaskan mengenai cara pemeriksaan dan penilaian kelengkapan serta kebenaran berkas permohonan izin edar alkes elektromedik dan non elektromedik dengan melihat informasi produk informasi spesifikasi dan jaminan mutu penandaan dan petunjuk penggunaan produk serta post market evaluation sesuai dengan yang tercantum dalam penerapan Indonesia National Single Window INSW di Kementerian Kesehatan Republik Indonesia Pendaftar mengajukan berkas permohonan izin edar berupa data administrasi dan data teknis beserta kelengkapannya sesuai dengan persyaratan yang tercantum dalam Peraturan Menteri Kesehatan Republik Indonesia No 1191 Menkes PER 2010

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Apothecary Internship at Directorate of Production and Distribution of Medical Devices as well as gain knowledge about the role of apothecary in the pharmaceutical care especially in the production and distribution of Medical Devices and medical supplies household PKRT Directorate of Production and Distribution of Medical Devices has a duty to carry out the preparation of the formulation and implementation of policies and preparation of Norms Standards Procedures and Criteria NSPK and providing technical guidance and evaluation in the field of production and distribution of medical devices and PKRT Apothecary role as the assessment team evaluates the file application for the product certificate license distributor medical devices and medical devices and PKRT authorization In specific task described on how the examination and assessment of the completeness and correctness files petition authorization electromedic and non electromedic medical devices to view product information specifications and quality assurance information product labeling and instructions for us as well as post market evaluation as indicated in the implementation of Indonesia National Single Window INSW in the Kementerian Kesehatan Republik

Indonesia Applicant filed an application for license file on the data in the form of administrative and technical data along with the accessories in accordance with the requirements set forth in the regulation of the Kementerian Kesehatan Republik Indonesia No 1191 Menkes PER 2010